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July 7, 1999

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

PETITION FOR STAY OF ACTION

Leiner Health Products ("Leiner") submits this petition to request that the Commissioner of Food and Drugs stay for one year the effective date of the final rule[1] requiring that labeling for over-the-counter ("OTC") nasal decongestant drug products change the name of the listed active ingredient l-desoxyephedrine to levmetamfetamine. Under the final rule, labeling must reflect this name change by July 30, 1999. Leiner is requesting a one-year extension of this date, because an unforeseen interruption in its raw material supply has left the company unable to deplete the existing labeling stock for its in-house brand and 22 private label customers. With the additional time, Leiner will be able to incorporate the name change during a future manufacturing cycle.

[1] 63 Fed. Reg. 40647 (July 30, 1998) (codified at 21 C.F.R. § 341.20).

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DECISION INVOLVED

On July 30, 1998, the Food and Drug Administration ("FDA") published a final rule amending the final monograph for OTC nasal decongestant drug products and requiring that labeling change the name of the active ingredient "l-desoxyephedrine" to "levmetamfetamine."[2] This name change reflects a new United States Pharmacopeia ("USP") monograph, which includes levmetamfetamine as the new name for what had formerly been l-desoxyephedrine. Although both FDA and the Drug Enforcement Administration ("DEA") objected to the name change, the USP adopted the new name based on the recommendation of the United States Adopted Names Council and its interpretation of International Nomenclature Name policies. 63 Fed. Reg. at 40648. FDA has identified no public health concerns requiring the chemical name change.

In adopting the USP's monograph and the name change, FDA provided for a one-year effective date, such that labeling must reflect the new established name by July 30, 1999. FDA set this effective date in order to allow manufacturers "sufficient time to incorporate the change during a future manufacturing cycle." 63 Fed. Reg. at 40649. As explained further below, Leiner has prepared and ordered new labeling; however, special circumstances have prevented Leiner from using its old labeling during the one-year period in which FDA envisioned such labeling would be used up.

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[2] Leiner files this petition for stay of action more than 30 days after FDA's publication of the final rule, and requests permission to file for good cause under 21 C.F.R. §§ 10.35(b) & (g). As explained in the text, the need for the stay Leiner now requests only recently became apparent when Leiner understood the extent and duration in the interruption of its raw material supply.

ACTION REQUESTED

Leiner requests that FDA extend until July 20, 2000 the deadline for changing the name of l-desoxyephedrine to levmetamfetamine on Leiner's OTC nasal decongestant products. This one-year extension will allow Leiner to use its current supply of product labeling and incorporate new labeling in future manufacturing runs as the current labeling is depleted.

STATEMENT OF GROUNDS

I. Leiner Has Been Unable to Deplete its Current Labeling Because of an Unforeseen Accident at the Factory of Its Raw Material Supplier.

FDA stated expressly when it promulgated the final rule requiring the change from l-desoxyephedrine to levmetamfetamine that it was providing a one-year effective date in order to allow manufacturers to make the change during future manufacturing runs. 63 Fed. Reg. at 40649. Leiner, like other manufacturers, moved promptly after publication of the rule to do precisely that, and in September 1998 began working on new labeling art and copy for its in-house brand and 22 private label clients. Unfortunately, despite Leiner's diligence, the company's transition plans for moving to the new labeling were derailed when its lone supplier of raw material suffered an explosion at its factory in August 1998 and halted all production.

Leiner's supplier has yet to come back on line, and Leiner has not been able to identify an alternate supplier of raw l-desoxyephedrine/levmetamfetamine in the meantime. As a result, Leiner has remained unable to manufacture finished product for months during the critical period leading up to the effective date of the final rule (July 30, 1999). Absent the explosion at its supplier's factory, Leiner would have exhausted its old labeling as part of its normal business cycle, just as FDA envisioned when assessing the impacts of its regulation. However, with the explosion Leiner is left with substantial stock of its old labeling (totaling over 380,000 units), which it has been unable to use because it has had no product to use it with. That existing

labeling inventory will become obsolete if Leiner is not given additional time to exhaust the inventory as its normal production finally resumes.

II. Good Cause Exists to Grant the Stay.

Under 21 C.F.R. § 10.35(e), FDA shall grant a stay where: (1) the petitioner will suffer irreparable injury without the stay; (2) the petitioner's case is not frivolous and is brought in good faith; (3) the petitioner has demonstrated sound public policy grounds in support of the stay; and (4) public health or other public interests do not outweigh the resulting delay. Leiner satisfies each of these criteria.

A. Leiner Will Suffer Irreparable Injury Without the Stay.

Without the stay Leiner will suffer irreparable economic injury. As stated above, Leiner still has over 380,000 units of old l-desoxyephedrine labeling on hand. This inventory is worth approximately $40,000 and, for many of Leiner's private label customers, represents a year or more of product labeling. All of this labeling will have to be discarded after July 30, 1999 if Leiner's petition is denied. Leiner would have no means by which to recoup this loss. Thus, forcing Leiner to cease using its inventory of old labeling would cause the company significant damages for which it would be without a remedy. No public health or other public policy grounds exist to justify imposition of this economic loss, as discussed further below.

B. Leiner's Petition is Bona Fide and Pursued in Good Faith.

Leiner's petition is neither frivolous nor pursued in bad faith. Leiner needs an extension of the effective date of FDA's final rule only because of the unfortunate and unforeseeable explosion at the factory of its raw material supplier. Indeed, Leiner has been proactive and extremely diligent in taking steps to comply with the new rule. Leiner began work on new labeling in September 1998, and that new labeling began arriving in December 1998.

However, once Leiner ran out of raw material after the August 1998 explosion, it was simply unable to use the labeling it had on hand.

Leiner has only recently realized that its uncertain supply situation will not change significantly before the July 30, 1999 deadline. Following the August 1998 explosion, Leiner had understood that its supplier would resume production without substantial delay. As the weeks passed by, Leiner received assurances that a resumption in production was imminent. However, that return of its raw material supply has perennially remained a week away.

Meanwhile, with the July 30, 1999 deadline drawing ever nearer, Leiner began ordering new labeling to ensure that it could comply with the new rule. At the same time, now that Leiner appreciates the magnitude of its labeling inventory backlog, it is pursuing this petition in order to avoid the waste of having to discard over 380,000 units of its old labeling. This waste would be particularly unjustified in this case, because the labeling change relates to a technical issue of chemical nomenclature and not a public health concern. Accordingly, Leiner has a good faith and bona fide basis for filing the petition.

C. Granting the Stay Would Avoid Economically Wasteful Actions and Promote the Objectives FDA Sought to Capture in Its Initial Rule.

Sound public policy grounds support the grant of a stay. In promulgating the final rule, FDA noted that the costs of the rule involved here were "not economically significant." 63 Fed. Reg. at 40649. However, this conclusion was premised on the assumption that some manufacturers had already changed their labels, and that "an effective date of 1 year . . . will provide manufacturers of the remaining products sufficient time to incorporate the name change during a future manufacturing cycle." *Id.* In the past year, Leiner has not enjoyed a normal manufacturing cycle, but instead saw its production crippled by an unforeseen event. The explosion of its supplier's factory has invalidated FDA's assumption that one year was an

adequate time period in which to make the transition in labeling, and consequently rendered FDA's conclusion that the cost of the rule is insignificant incorrect in Leiner's case. FDA's own stated objective of allowing manufacturers sufficient time to incorporate the new labeling during a normal manufacturing cycle will only be met if Leiner is granted additional time for complying with the required name change.

Granting the stay would also promote good regulatory policy in accordance with Executive Order 12,866, which directs agencies to "assess all costs and benefits of available regulatory alternatives" and "select those approaches that maximize net benefits." Here, rigid adherence to the July 30, 1999 deadline will impose wasteful costs on Leiner with no corresponding public benefit, while granting a stay will avoid the costs with no corresponding public harm. Thus, FDA can minimize the adverse impact of its regulation without jeopardizing the public interest and "maximize net benefits" by granting Leiner's petition.

D. No Countervailing Public Health or Other Considerations Require Denial of the Leiner's Stay Request.

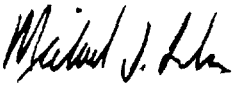
As alluded to throughout this petition, no public health or other public interest considerations compel denial of the stay. Unlike other regulations, the final rule at issue here was driven by a technical issue of chemical nomenclature following the USP's adoption of a new monograph, and was not spurred by any pressing public health concern. Indeed, FDA and DEA even opposed the name change for fear that adoption of the name "levmetamfetamine" might encourage the diversion of legal drug products for use in the illicit manufacture of methamphetamine. 63 Fed. Reg. at 40648. Although FDA has ultimately adopted the new chemical name, it identified no public health or public policy basis for its regulation other than the desire to track the new USP monograph. Accordingly, no public health risk is created by allowing Leiner a limited additional period of time in which to deplete its old labeling, just as no

risk was created by FDA's initial determination to allow companies to use old labeling for one year notwithstanding the Agency's amendment of the final monograph for OTC nasal decongestants.

CONCLUSION

For the foregoing reasons, the requested stay of action should be granted.

Respectfully submitted,



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